IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
DELTA DIVISION

ANNA K. EARLS — PLAINTIFF

V. — 2:07CV00085-B-A

BLUE CROSS AND BLUE SHIELD
OF ALABAMA, INC. — DEFENDANT

MEMORANDUM OPINION

This cause comes before the court upon the defendant's motion for summary judgment. Upon due consideration of the motion, response, exhibits, and supporting and opposing authority, the court is ready to rule.

Factual and Procedural Background

On April 5, 2007, the plaintiff, Anna K. Earls, a former employee of BellSouth Telecommunications, Inc., and a participant in the BellSouth Retiree Medical Assistance Plan for BellSouth Employees, brought this action in the Circuit Court of the Second Judicial District of Bolivar County, Mississippi, alleging that the defendant, Blue Cross and Blue Shield of Alabama, Inc., wrongfully denied medical benefits. Because the plan is governed by ERISA[1], the defendant properly removed the case to this court on the ground of preemption.

The plaintiff suffered from severe migraine headaches and began seeking treatment for her condition in May 2003. Various prescribed medication and other forms of therapy proved to be unsuccessful, and in September 2005, Dr. Adam Lewis suggested that the plaintiff try the implantation of a neurostimulator in her occipital lobe. The plaintiff agreed and underwent outpatient surgery for a trial implantation on September 8, 2005, at St. Dominic-Jackson

[1]Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001-1461.

Memorial Hospital in Jackson, Mississippi. The plaintiff was readmitted to St. Dominic for permanent implantation of a neurostimulator four days later on September 12. Both the hospital and the surgeon submitted claims to the defendant for the expenses of both surgeries.

The plan under which the plaintiff seeks benefits expressly excludes from coverage "[i]nvestigational treatment, procedures, facilities, drugs, drug usage, equipment, or supplies including services that are part of a clinical trial." The plan defines the term "investigational" as follows:

> Any treatment, procedure, facility, equipment, drugs, drug usage, or supplies that either we have not recognized as having scientifically established medical value, or that does not meet generally accepted standards of medical practice. When possible, we develop written criteria (called medical criteria) concerning services or supplies that we consider to be investigational. We base these criteria on peer-reviewed literature, recognized standards of medical practice, and technology assessments. We put these medical criteria in policies that we make available to the medical community and our members. We do this so that you and your providers will know in advance, when possible, what we will pay for. If a service or supply is considered investigational according to one of our published medical criteria policies, we will not pay for it. If the investigational nature of a service or supply is not addressed by one of our published medical criteria policies, we will consider it to be non-investigational only if the following requirements are met:
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> - The technology must have final approval from the appropriate government regulatory bodies;
> - The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
> - The technology must improve the net health outcome;
> - The technology must be as beneficial as any established alternatives; and,
> - The improvement must be attainable outside the investigational setting.
>
> It is important for you to remember that when we make determinations about the investigational nature of a service or supply we are making them solely for the purpose of determining whether to pay for the service or supply. All decisions

> concerning your treatment must be made solely by the attending physician and other medical providers.

Dr. Pat Rice, the defendant's Rule 30(b)(6) representative, testified in deposition that under these criteria "the occipital neurostimulator for the treatment of cluster or migraine headaches is now and has always been considered investigational by Blue Cross and Blue Shield of Alabama." Dr. Rice testified and documents in the record reflect that the defendant determined in August 2003 – two years prior to the plaintiff's surgeries – that "[c]ranial nerve stimulator or occipital nerve stimulator for the treatment of cluster headaches is considered investigational."

The hospital's and surgeon's claims relating to the plaintiff's 9/12/05 permanent implantation, the surgeon's 9/8/05 trial implantation claim, and the anesthesia claims related to the surgeries were denied as excluded from coverage as part of an investigational procedure. The hospital's 9/7/05 claim was paid in October 2005, but only as the result of a clerical error in the hospital's filing of the claim. The error was not discovered by the defendant until this litigation began, and the defendant is not attempting to recoup the payment.

The plaintiff and providers appealed the denial of the claims. A Blue Cross medical examiner, Dr. James Davis, reviewed the file and also concluded that the procedure did not meet the necessary medical criteria for payment. The plaintiff's surgeon, Dr. Lewis, then faxed a letter to Blue Cross which included research from the Mayo Clinic regarding the use of occipital nerve stimulation for the treatment of chronic headaches. In July 2006, Blue Cross forwarded all of this information to MCMC, an independent medical review company not affiliated with Blue Cross. Dr. Michael Hoffman of MCMC, a physician board certified in neurological surgery, reviewed the file, including the literature from Dr. Lewis, as well as the recently published

literature on the topic and concluded that the use of occipital nerve stimulators for migraine headaches is experimental and investigational. Noting that the Mayo Clinic study involved only sixteen patients, Dr. Hoffman concluded that "there are no randomized controlled studies with statistically significant numbers of patients published in the peer-reviewed medical literature showing efficacy."

The plaintiff's attorney requested further review of the decision, and after such review, Blue Cross determined that the claims should still be denied as investigational. According to Dr. Pat Rice, to this date, the major national administrators, including CIGNA, Aetna, and Blue Cross, consider the procedure to be investigational.

As noted above, the plaintiff filed the present suit in state court on April 5, 2007, and the defendant subsequently removed to this court, citing ERISA preemption. The defendant has now moved for summary judgment.

Summary Judgment Standard

A party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). On a motion for summary judgment, the movant has the initial burden of showing the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S. Ct. 2548, 2554, 91 L. Ed. 2d 265 (1986). If the movant makes such a showing, the burden then shifts to the non-movant to "go beyond the pleadings and by . . . affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex Corp.*, 477 U.S. at 324,

106 S. Ct. at 2553, 91 L. Ed. 2d at 274 (quoting Fed. R. Civ. P. 56(c), 56(e)). Before finding that no genuine issue for trial exists, the court must first be satisfied that no rational trier of fact could find for the non-movant. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538, 552 (1986).

ERISA Standard

If an ERISA plan gives the administrator "discretionary authority to determine eligibility for benefits or to construe the terms of the plan," challenges to a denial of benefits are reviewed under an abuse of discretion standard. *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). "Discretionary authority cannot be implied; an administrator has no discretion to determine eligibility or interpret the plan unless the plan language expressly confers such authority on the administrator." *Wildbur v. ARCO Chem. Co.*, 974 F.2d 631, 636 (5th Cir. 1992). "When a plan gives such discretion, a district court will overrule the plan administrator's interpretation of plan terms only if the interpretation is 'arbitrary and capricious.'" *Matassarin v. Lynch*, 174 F.3d 549, 563 (5th Cir. 1999). The difference between an "abuse of discretion" standard of review and an "arbitrary and capricious" standard of review is semantic, not substantive. *Wildbur*, 974 F.2d at 635.

The plan at issue in this case expressly gives the claims administrator discretionary authority. The pertinent language from the plan states as follows:

> Delegation of Discretionary Authority to Blue Cross
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> The employer has delegated to us the discretionary responsibility and authority to determine claims under the plan, to construe, interpret, and administer the plan, and to perform every other act necessary or appropriate in connection with our provision of administrative services under the plan. Whenever we make reasonable determinations that are neither arbitrary or capricious in our administration of the plan, those

> determinations will be final and binding on you, subject only to your right of review under the plan and thereafter to judicial review to determine whether our determination was arbitrary or capricious.

This court, therefore, reviews the administrator's decision for abuse of discretion.

Analysis

In reviewing the administrator's decision, the court employs a two-step analysis. *Id.* at 637. First, the court must determine the legally correct interpretation of the plan. *Id.* To determine whether the administrator's interpretation was legally correct, the court must consider "(1) whether the administrator has given the plan a uniform construction, (2) whether the interpretation is consistent with a fair reading of the plan, and (3) any unanticipated costs resulting from different interpretations of the plan." *Id.* at 637-38. If the court finds that the administrator did not give the plan the legally correct interpretation, then the court must determine whether the administrator abused his discretion. *Id.* at 638. The court considers three factors in this analysis: "(1) the internal consistency of the plan under the administrator's interpretation, (2) any relevant regulations formulated by the appropriate administrative agencies, and (3) the factual background of the determination and any inferences of lack of good faith." *Id.*

Examining the factors relevant to determining the legally correct interpretation of the plan, the court first finds that the defendant has given the plan a uniform construction. Robin Hester, the defendant's "Quality Care Coordinator," testified in deposition that Blue Cross has not approved the use of neurostimulators for migraine headaches under the BellSouth plan. The plaintiff asserts that other Blue Cross plans have covered this procedure in other cases but fails to direct the court to proof of such instances. If the court were addressing these issues in a Rule 12(b)(6) context, taking all of the plaintiff's allegations as true, such an assertion could possibly

help the plaintiff survive dismissal. Conclusory and unsubstantiated allegations are insufficient at the summary judgment stage, however. *See, e.g., Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1429 (5th Cir. 1996) (stating that "conclusory allegations, speculation, and unsubstantiated assertions are inadequate to satisfy the nonmovant's burden" at the summary judgment stage of a case); *Turner v. Baylor Richardson Medical Center*, 476 F.3d 337, 343 (5th Cir. 2007) (stating that a "party cannot defeat summary judgment with conclusory allegations, unsubstantiated assertions, or 'only a scintilla of evidence'").

Next the court addresses whether the defendant's denial of benefits is consistent with a fair reading of the plan. The court finds that it is. "Investigational treatment, procedures, facilities, drugs, drug usage, equipment or supplies including services that are part of a clinical trial" are expressly excluded from coverage, and the evidence before the court, addressed in more detail below, indicates that the plaintiff's procedure was correctly deemed investigational.

Third, the court considers unanticipated costs resulting from different interpretations of the plan. If Blue Cross were required to authorize payment for investigational procedures such as the plaintiff's claim, the plan would undoubtedly encounter considerable unanticipated costs. The record reflects that the plaintiff's claim alone would require payment of approximately $100,000.00, were Blue Cross required to pay. Because Blue Cross considers this procedure investigational and expressly excludes investigational procedures from the plan, these costs would certainly be unanticipated.

For these reasons, the court finds that the administrator's interpretation of the plan is legally correct. Because a legally correct interpretation of a plan cannot be an abuse of

discretion[2], the court could end its inquiry here but instead chooses also to examine whether the administrator could be deemed to have abused its discretion if, for the sake of argument, the court had reached a different conclusion regarding the interpretation's legal correctness.

The abuse of discretion standard of review is a highly deferential standard. The Fifth Circuit has held that an administrator's decision must be upheld under the abuse of discretion standard as long as the decision "fall[s] somewhere on a continuum of reasonableness – even if on the low end." *Vega v. Nat'l Life Ins. Serv., Inc.*, 188 F.3d 287, 297 (5th Cir. 1999). "[T]he administrator's decision must be supported by substantial evidence in the administrative record, which is evidence that a reasonable mind might accept as sufficient to support a conclusion." *Wade v. Hewlett-Packard Development Co. LP Short Term Disability Plan*, 493 F.3d 533 (5th Cir. 2007).

The court finds substantial evidence in the administrative record to support the administrator's conclusion that the plaintiff's procedure was investigational and therefore excluded from coverage. First, the record reflects that the implantation of a neurostimulator for the treatment of headaches was deemed investigational by the defendant as early as 2003 – two years before the plaintiff's surgeries. Second, the decision is supported by the plan's written criteria which indicate that the plaintiff's procedure is investigational under the terms of the plan. Third, Dr. James Davis, a Blue Cross medical examiner, concluded that the procedure was investigational for the treatment of migraine headaches. Fourth, Dr. Michael Hoffman, an independent medical reviewer who is board certified in neurological surgery, concluded that the

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[2]*See, e.g., Tolson v. Avondale Indus., Inc.*, 141 F.3d 604, 608 (5th Cir. 1998) ("We need not proceed to the second step of the *Wildbur* analysis to search for abuse of discretion if we determine in applying the first step that the plan administrator's legal interpretation of the plan provisions is correct.")

procedure was investigational for the treatment of migraine headaches. In doing so, Dr. Hoffman noted the lack of statistically significant data on the procedure's efficacy. Finally, though this evidence does not appear to have been part of the administrative record, the court is further persuaded by evidence showing that the major carriers, including CIGNA, Aetna, and Blue Cross, all consider the procedure investigational for the treatment of migraine headaches. The plaintiff has submitted no evidence that any insurer covers the procedure for the treatment of migraine headaches, though she did make an unsubstantiated, conclusory allegation that other Blue Cross plans cover the procedure.

The plaintiff's primary argument in response to the defendant's summary judgment motion is derived from the Second Circuit case of *Zervos v. Verizon New York, Inc.*, 277 F.3d 635 (2d Cir. 2002). In *Zervos* the plan administrator had denied coverage for high dose chemotherapy for an insured who had been diagnosed with metastatic breast cancer on the ground that the treatment was investigational. *Zervos*, 277 F.3d at 638. The plan required that a treatment be as effective, not more effective, than alternative treatments in order to avoid exclusion under the policy's investigational language. *Id.* at 647. The reviewing doctor, Dr. Wollinsky, had incorrectly required that the treatment be superior to another existing treatment. *Id.* Finding that the high dose chemotherapy was not superior to other forms of treatment, the administrator denied coverage on the basis of the investigational treatment exclusion. *Id.* "Thus, contrary to basic ERISA principles, Dr. Wollinsky in effect added additional language to the policy." *Id.* The Second Circuit found the denial of coverage to be arbitrary and capricious for this reason. *Id.*

Citing *Zervos*, the plaintiff in the case at bar argues that by requiring the number of patients involved in the published clinical trials to be "statistically significant," Dr. Hoffman has inappropriately added language to the plan, and summary judgment should, therefore, be denied. The court is unpersuaded by the plaintiff's argument. Among the criteria outlined in the plan which are used to determine whether a procedure is investigational is the requirement that "[t]he scientific evidence must permit conclusions concerning the effect of the technology on health outcomes." The plan further provides that Blue Cross develops its criteria based on "peer-reviewed literature, recognized standards of medical practice," to determine whether the procedure at issue has "scientifically established medical value." A very basic expectation in determining whether the medical value of a procedure is "scientifically established" would be that the clinical studies relied upon have scientific value. Clearly, to have scientific value, the studies must be controlled and with a sufficient number of subjects to permit a conclusion that the procedure at issue alleviates the medical condition at issue. The court finds that Dr. Hoffman did not add language to the plan in violation of ERISA, and that *Zervos* is not sufficiently analogous to the present case to be persuasive.

The court finds that the administrator did not abuse its discretion by denying coverage based on its conclusion that the implantation of occipital neurostimulators for the treatment of migraine headaches is investigational. The court also finds the administrator's interpretation of the plan to be legally correct. For these reasons, the defendant is entitled to judgment as a matter of law.

The procedure at issue obviously works for some people, including the plaintiff, who suffer from migraine headaches. Unfortunately, the present state of research on the matter is

inadequate to take the procedure beyond the realm of investigational. The court, therefore, must determine that the administrator made the correct decision.

Conclusion

For the foregoing reasons, the court finds that no genuine issue of material fact exists in this case, and the defendant is entitled to judgment as a matter of law. A separate order in accord with this opinion shall issue this day.

This, the 30th day of April, 2008.

/s/ Neal Biggers

NEAL B. BIGGERS, JR.
SENIOR U.S. DISTRICT JUDGE